



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,301	05/30/2007	Jun-Keun Chang	LT00012 US	3208

52059 7590 08/09/2011
LIFE TECHNOLOGIES CORPORATION
5791 Van Allen Way
Carlsbad, CA 92008

EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
----------	--------------

1775

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

08/09/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LifetechDocket@system.foundationip.com
paralegals@system.foundationip.com

Office Action Summary	Application No. 10/560,301	Applicant(s) CHANG ET AL.	
	Examiner WILLIAM H. BEISNER	Art Unit 1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-28 and 43-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-28 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 June 2011 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/12/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 4/12/2011 has been considered and made of record.

Drawings

2. Corrected drawings of Figures 1 and 2 were received on 6/7/2011. These drawings are acceptable.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 25-28, 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 25, the recited “an electrode terminal for electrically connecting the fixing unit” is indefinite because is it not clear how the fixing unit electrically participates in the generation of electric pulses. That is the claim recites a fixing unit and an electrode terminal for electrically connecting the fixing unit but is silent as to how the electrode terminal and/or fixing unit are connected to the other positively recited components so as to provide the electric pulses to the cells for

Art Unit: 1775

electroporation. Does the fixing unit function as an electrode for electroporation?. As a result, the metes and bounds of the claim cannot be clearly determined.

With respect to claim 26, how does the “conductive contact” structurally cooperate with the previously recited "an electrode terminal", if at all? The same holds true for the movable electrode. In the lack of any positively recited structural cooperation between the “conductive contact” and/or “movable electrode” the metes and bounds of the claim cannot be clearly determined.

Note claims 27, 28, 44 and 45 are deemed indefinite in view of their dependency on indefinite claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 18-25, 27, 28 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Preece et al.(EP 0 338 667).

With respect to claim 18, the reference of Preece et al. discloses a device that is capable of electroporation (Figure 1) that includes a long hollow specimen-stuffing member (14) of non-conductive material; a reservoir (24,32) connected to a distal end of the specimen-stiffing member (14) for fluid communication; and a pressure maintaining means (syringe, 28) connected to the other distal end of the specimen-stuffing member

Art Unit: 1775

(14) for fluid communication. It is noted that on pages 7-8 of the reply filed 6/7/2011 Applicants have indicated that 35 USC 112, 6th paragraph, has been invoked and that “a pressure maintaining means” can be a syringe.

With respect to claim 19, the specimen-stuffing member (14) has a ratio of length to cross-sectional area in the range of 50-10,000 (See column 3, lines 45-50).

With respect to claim 20, the hollow specimen-stuffing member (14) is a capillary tube.

With respect to claims 21 and 22, the pressure maintaining means (28) is connected by a connector (10) disposed with an electrode insertion unit (20) for inserting an electrode (18) which can electrically contact a specimen held in specimen-stuffing member (14).

With respect to claim 23, upper member (10) with lateral electrode insertion (20) of the reference of Preece et al. meets the structure recited in claim 23.

With respect to claim 24, the pressure maintaining means (28) is a syringe.

With respect to claim 25, the reference of Preece et al. discloses a device that is capable of electroporation (Figure 1) that includes a long hollow specimen-stuffing member (14) of non-conductive material; a reservoir (24,32) with an electrode (18) connected to a distal end of the specimen-stuffing member (14) for fluid communication; a pressure maintaining means (28) connected to the other distal end of the specimen-stuffing member (14) for fluid communication; and a reservoir holder (10) for holding or fixing the reservoir (24, 32) and the pressure maintaining means (28) and includes electrode terminals projecting from chambers (20).

Art Unit: 1775

With respect to claim 27, the hollow specimen-stuffing member (14) is a capillary tube.

With respect to claim 28, the specimen-stuffing member (14) has a ratio of length to cross-sectional area in the range of 50-10,000 (See column 3, lines 45-50).

With respect to claim 43, the device of Preece et al. also includes a pulse generator (36).

Allowable Subject Matter

5. Claims 26, 44 and 45 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter:

Claims 26, 44 and 45 would be allowable because the prior art of record fails to teach or fairly suggest the combination of elements recited in claims 26 and 45 that additionally include a pipette/piston device wherein the electrode is movable and connected with the pipette piston.

Response to Arguments

7. With respect to the rejection of Claims 18-28 and 43-45 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

Art Unit: 1775

claim the subject matter which applicant regards as the invention, Applicants argue that the rejections are improper for the following reasons:

a) With respect to claims 18 and 25, Applicants stress that the specification clearly describes what structural components would be encompassed by the language “pressure maintaining means” (See pages 7-8 of the response filed 6/7/2011).

In response, the rejection of these claims has been withdrawn.

b) With respect to the lack of antecedent basis for claims 21 and 25, the rejection of these claims has been withdrawn in view of Applicants’ amendments to the claims and related comments (See page 8 of the response filed 6/7/2011).

c) With respect to the rejection of claim 25, Applicants argue that the claim is not indefinite because support for the claim limitation can be found in the specification (See pages 8-10 of the response filed 6/7/2011).

In response, Applicants’ comments are not found to be persuasive because while “understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claims” (See MPEP 2111.01 II). In this case, in view of the current claim language it is not clear how the device recited in claim 25 is structurally capable of functioning as an electroporation apparatus without a positively recited electrode that cooperates with the single positively recited electrode so as to electroporate a cell sample.

d) With respect to the rejection of claim 26, Applicants argue that the claim is not indefinite because support for the claim limitation can be found in the specification (See pages 10-11 of the response filed 6/7/2011).

In response, Applicants' comments are not found to be persuasive because while "understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claims" (See MPEP 2111.01 II). In this case, in view of the current claim language it is not clear how the further structural elements recited in claim 26 electrically connect to the elements previously recited in claim 25, if at all.

8. With respect to the rejection of Claims 18-25, 27, 28 and 43 under 35 U.S.C. 102(b) as being anticipated by Preece et al. (EP 0 338 667), Applicants argue that the rejection is improper for the following reasons:

a) The reference of Preece et al. is not "an electroporation apparatus". Applicants stress that the device of Preece et al. is an electrofusion device and therefore cannot anticipate claims 18 and 25 (See page 12, paragraph 2, of the response filed 6/7/2011).

In response, as stated in the 35 USC 102 rejection of record, the device disclosed by the reference of Preece et al. is the same as that recited in claims 18 and 25. In this case, the body of the claim fully sets forth all the limitations of the claims and the preamble merely sets for the purpose or intended use of the device. Additionally, the structure of the device of Preece et al. is structurally capable of performing electroporation. Note the newly cited reference of Takahashi et al. (US 5,007,995) which evidences that a device constructed for electrofusion is also a device capable of electroporation (See column 2, lines 43-46).

b) The reference of Preece et al. does not disclose any of the elements of claims 18 and 25. Applicants stress that elements 24 and 32 of Preece et al. are not “reservoirs” (See pages 12-13 of the response filed 6/7/2011).

In response, the Examiner maintains that all of the claimed elements of claims 18 and 25 are met by the reference of Preece et al. for the reasons already set forth in the 35 USC 102 rejection of record. It is noted that while the reference of Preece et al. does not identify elements 24 or 32 as “reservoirs”, they hold liquid during use and meet the structure of a reservoir. Instant claims 18 and 25 do not further distinguish the structure of the claimed reservoir over the structure of elements 24 or 32 of Preece et al..

c) The tube and syringe of Preece et al. are used in a different manner than in the instant invention (See page 13 of the response filed 6/7/2011).

In response, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

d) The instant invention encompassed by claims 18 and 25 result in superior results when compared to the device of Preece et al. (See pages 13-14 in the response filed 6/7/2011).

In response, as stated previously, the structure of the device disclosed by that of the reference of Preece et al. is the same as that instantly claimed and clearly capable of functioning as a device for electroporation for reasons already stated on the record and since a device for electrofusion is a device for performing electroporation. Further note that the instant claims are rejected under 35 USC 102 and evidence of secondary

Art Unit: 1775

consideration showing unexpected or superior results cannot be used to overcome an anticipatory rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Takahashi et al. (US 5,007,995).

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

Art Unit: 1775

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael A. Marcheschi, can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1775**

WHB